

R E M A R K S

Applicants propose to amend claims 20-22 and 24-27. Upon entry of these amendments, claims 20-28 remain pending. Applicants submit that entry of these amendments after final is appropriate because these amendments address and overcome the indefiniteness rejections. Applicants appreciate the withdrawal of many of the previous prior art rejections. The remaining rejections are discussed below.

The claimed invention is not taught by Pipe (with Lollar) or Lollar alone

On pages 2-3 of the office action, the examiner made two anticipation rejections. Applicants respectfully traverse these rejections.

Applicants note that in order to reject a claim under 35 USC § 102, the examiner must demonstrate that each and every claim term is contained in a single prior art reference. See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986); see also MPEP § 2131 (Rev. 1, February 2003). Claim terms are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. See MPEP §§ 707.07(g); 2111.01 (August 2001). Claims are to be given their broadest reasonable interpretation consistent with applicants' specification. See *In re Zletz*, 13 USPQ2d 1320, 1322 (Fed Cir. 1989) (holding that claims must be interpreted as broadly as their terms reasonably allow); MPEP § 2111 (Rev. 1, February 2003).

Not only must the claim terms, as reasonably interpreted, be present, an allegedly anticipatory reference must enable the person of ordinary skill to practice the invention as claimed. Otherwise, the invention cannot be said to have been already within the public's possession, which is required for anticipation. See *Akzo, N.V. v. U.S.I.T.C.*, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986); *In re Brown*, 141 USPQ 245, 249 (CCPA 1964). Applicants review below the references with these concepts in mind.

Pipe (with Lollar)

The examiner rejected claims 20 and 23 as anticipated by Pipe as evidenced by Lollar. The examiner, however, did not provide any reasoning to support the rejection, and therefore the rejection does not comply with 37 CFR § 1.104.

The examiner has attempted to combine Pipe with Lollar in an anticipation rejection. The use of multiple references in an anticipation rejection is governed by MPEP § 2131.01 (Rev. 1, February 2003), and is permitted only under very limited circumstances that do not seem to have been met in the present rejection. Again, the examiner provides no explanation of the rejection.

In any event, Pipe discloses substitutions only in a C2 domain. Pipe does not disclose any substitutions in an A3 domain, which is a requirement of claims 20 and 23. Accordingly, Pipe cannot meet each and every limitation of the claims, and therefore Pipe cannot anticipate the claims. Applicants therefore request withdrawal of the rejection.

Lollar

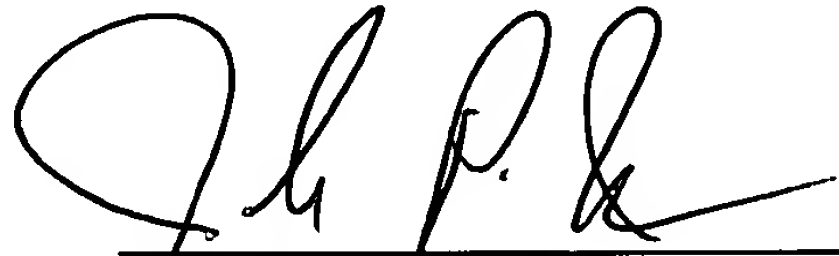
The examiner rejected claims 20 and 22 as anticipated by Lollar. According to the examiner, Lollar discloses a hybrid protein formed by fusing a human factor VIII heavy chain with a porcine factor VIII light chain. There are no changes in the domains of the porcine light chain *per se*. The present claims, however, require certain modifications within defined portion(s) or one or more of the domains of the light chain, based upon the human sequence. Given that Lollar does not disclose the recited modifications within a light chain domain, but rather teaches a wholesale 'swapping' of light chain domains between proteins from different species, it is very clear that the present claims and Lollar pertain to very different subject matter.

Applicants respectfully submit that Lollar cannot anticipate the claims and therefore a rejection based upon Lollar cannot be maintained. Applicants respectfully request withdrawal of the rejection.

Request

Applicants submit that the claims are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'John P. Isacson', written over a horizontal line.

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